

# PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of  
**Mary et al**  
Application No.: **Not Yet Assigned**  
Filed: **Filed Concurrently Herewith**  
Title: **NOVEL THERAPEUTIC APPLICATION  
OF ENOXAPARIN**

Examiner: L. Maier

Art Unit: 1623

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

**May 19, 2004**

Date of Deposit

Bonnie Stein  
Signature

**EL 964823525 US**

Express Mail No.

### INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. 1.56, 1.97 AND 1.98

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Applicants submit herewith patents, publications, and other information of which they are aware, which they believe may be material, as defined in 37 C.F.R. 1.56(b), to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 C.F.R. 1.56(a). While the information referred to in this Information Disclosure Statement may be material pursuant to 37 C.F.R. 1.56(b), the filing of this Information Disclosure Statement is not intended to, pursuant to 37 C.F.R. 1.97(h), constitute an admission that any patent, publication or other information referred to is, or is considered to be, material to the patentability of this invention. Pursuant to 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information exists.

- ☒ (a) This Information Disclosure Statement is filed within the period set forth in §1.97(b) because it accompanies the new patent application submitted herewith, is filed within three months of the filing date of a national application or within three months of the date of entry of the national stage as set forth in §1.491 in an international application, or is believed to be filed before the mailing date of a first Office Action on the merits, whichever event occurs last. However, in the event that the first office action has been mailed, the Commissioner is authorized to charge any fees under 37 C.F.R. 1.17(p) or credit any overpayment to Account No. **18-1982**.

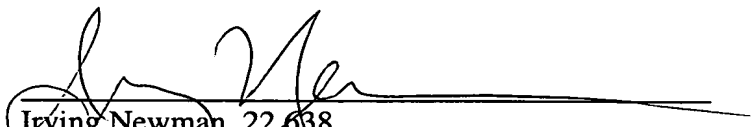
- ☐ (b) This Information Disclosure Statement is filed after the period set forth in 37 C.F.R. 1.97(b), but is believed to be filed before the mailing date of a final action under §1.113 or a notice of allowance under §1.311, whichever occurs first.
- ☐ (1) The undersigned attorney certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement;
- ☐ (2) The undersigned attorney certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned attorney after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this statement; or
- ☐ (3) This Information Disclosure Statement is accompanied by a transmittal letter in which payment of the fee set forth in §1.17(p) and required by 37 C.F.R. 1.97(c) is authorized.

The items listed with an asterisk on the attached PTO-1449 (modified) have been previously submitted by the applicant or cited by the Examiner in related applications of this series:

US Application No. 09/752,926

Therefore, a copy of the reference(s) are not enclosed with this Information Disclosure Statement.

Respectfully submitted,

  
Irving Newman, 22,638  
Attorney for Applicant

Aventis Pharmaceuticals Inc.  
Patent Department  
Route #202-206 / P.O. Box 6800  
Bridgewater, NJ 08807-0800  
Telephone (908) 231-2785  
Telefax (908) 231-2626  
Aventis Docket No. ST00001US CNT

☒

+

Substitute for form 1449A/PTO

*(use as many sheets as necessary)*

Sheet

1

of

4

## Application Number

Not Yet Assigned

Filing Date

Filed Concurrently Herewith

**First Named Inventor**

STUTZMANN

Group Art Unit

1623

**Examiner Name**

L. Maier

Attorney Docket Number

ST00001 - US - CNT

[illegible][illegible]

Date \_\_\_\_\_

**Considered**

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231.

+

Please type a plus sign (+) inside this box → ☒

PTO/SB/08B (10-96)  
Approved for use through 10/31/99. OMB 0651-0031  
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE  
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO			<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			Application Number	Not Yet Assigned
			Filing Date	Filed Concurrently Herewith
			First Named Inventor	STUTZMANN
			Group Art Unit	1623
			Examiner Name	L. Maier
			Attorney Docket Number	ST00001 - US - CNT
Sheet	2	of	4	

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		*AGG. TURPIE et al, THE LANCET; 1987; pp. 523-526	
		*BATH et al, Low Molecular Weight Heparin in Acute Stroke, EXPERT OPINION INVEST. DRUGS; Vol. 7; No. 8; 1998; pp. 1323-1330	
		*DAHL Trond et al, Dalteparin in Acute Ischemic Cerebrovascular Disease: A Safety Study, CEREBROVASCULAR DISEASES; Vol. 7; No. 1; 1997; pp. 23-33	
		*ELIAS et al, LA REVUE DE MEDECINE INTERNE; 1; Vol. XI; 1990; pp. 95-98	
		FAREED J et al, Biochemical and Pharmacologic Inequivalence of Low Molecular Weight Heparins, Ann. NY Acad. Sci., Vol. 556, 1989, pp 333-353	
		*GORDON David Lee et al., Low Molecular Weight Heparins and Heparinoids and Their Use in Acute or Progressing Ischemic Stroke, CLIN. NEUROPHARMACOL.; Vol. 13; No. 6; 1990; pp. 522-544	
		*HARDENBERG et al, Enoxaparin is Superior to Unfractionated Heparin in the Prevention of Thromboembolic Events in Medical Patients at Increased Thromboembolic Risk, BLOOD; Vol. 94; No. 10pt1.suppl.1; Abstract 1767; 1999; pp. 399a	
		*HILLBORN M et al, Comparison of the Efficacy of the Low Molecular Weight Heparin Enoxaparin with Unfractionated Heparin in the Prevention of Deep vein Thrombosis in Patients with a Cute Ischemic Stroke, BLOOD; Vol. 94; No. 20. Supl, pt1; abstract no.798; Nov. 15,1999; pp. 183a	
		*JIANYOU et al, Low-Mol.-Wt. Heparin in Treatment of Acute Cerebral Infarction, CHEMICAL ABSTRACTS; Vol. 127; No. 24; Abstract No. 326219z; 1997; pp. 54	
		JONAS S et al, Is Low Molecular Weight Heparin a Neuroprotectant, Annal New York Academy of Sciences, Vol. 825, Oct. 1997, pp 389-393	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → ☒

PTO/SB/08B (10-96)  
Approved for use through 10/31/99. OMB 0651-0031  
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE  
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				Application Number	Not Yet Assigned
				Filing Date	Filed Concurrently Herewith
				First Named Inventor	STUTZMANN
				Group Art Unit	1623
				Examiner Name	L. Maier
Sheet	3	of	4	Attorney Docket Number	ST00001 - US - CNT

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		*KAY et al, Low-Molecular-Weight Heparin for the Treatment of Acute Ischemic Stroke, NEW ENGLAND J. MED.; Vol. 333; No. 24; 1995; pp. 1588-1593	
		*KAY et al, Pilot Study of Low Molecular Weight Heparin in the Treatment of Acute Ischemic Stroke, STROKE; Vol. 25; No. 3; 1994-03; pp. 684-685	
		*LI Ping-An et al., Posttreatment with Low Molecular Weight Heparin Reduces Brain Edema and Infarct Volume in Rats Subjected to Thrombotic Middle Cerebral Artery Occlusion, BRAIN RES.; Vol. 801; No. 1-2; 1998; pp. 220-223	
		*PRATT J et al., Enoxaparin reduces cerebral edema after photothrombotic injury in the rat, HAEMOSTASIS, 1998, Vol. 28, pages 78-85	
		*PRINS et al, Prophylaxis of Deep Venous Thrombosis with a Low Molecular Weight Heparin (Kabi 2165/Fagmin) in Stroke Patients, HAEMOSTASIS; Vol. 19, No. 5; 1989; pp. 245-250	
		*RYU et al, Heparin Reduces Neurological Impairment After Cerebral Air Embolism in the Rabbit, STROKE; Vol. 27; No. 2; 1996; pp. 303-310	
		*SAMANA M M et al., Acute Ischemic Stroke and Heparin Treatments, THROMB. HAEMOSTASIS; Vol. 78; No. 1; 1997; pp. 173-179	
		*STULLKEN ET AL, The Effects of Heparin on Recovery from Ischemic Brain Injuries in Cats, ANESTH. ANALOG; Vol. 55; No. 5; 1976; pp. 683-687	
		*TAIST INVESTIGATORS, Tinzaparin in Acute Ischemic Stroke Trial (TAIST), STROKE; Vol. 30; No. 1; 1999-01; pp. 163	
		*YANAKA et al , Reduction of Brain Injury Using Heparin to Inhibit Leukocyte Accumulation in a Rat Model of Transient Focal Cerebral Ischemia. II. Dose-Response Effect and the Therapeutic Window, J. NEUROSURG.; Vol. 85, No. 6; 1996; pp. 1108-1112	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+

+

+

+++

+

+

+